

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

GRAM ET AL.

PATENT NO: 7,615,609

ISSUED: November 10, 2009

FOR: PREPARATION OF SOMATOSTATIN PEPTIDES

**MS: General**

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT-POST-GRANT

Sir:

In accordance with 37 C.F.R. § 1.705(d), Applicant hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of 200 days. This application is being filed within two months of the date the patent issued, as required by 37 C.F.R. § 1.705 (d).

**I. Fee**

As required by 37 C.F.R. § 1.705(b)(1), please charge Deposit Account No. 19-0314 for \$200.00 to cover the required fee (as defined in 37 C.F.R. § 1.18(e)). Please charge any deficiencies or any additional fees due in response to this request to Deposit Account 19-0314.

**II. Statement of the Facts Involved**

**A. Correct Patent Term Adjustment**

Applicant received the Issue Notification mailed June 24, 2009. United States Patent No. 7,615,609 issued on November 10, 2008, indicating a patent term adjustment of 136 days.

Patentee has calculated a patent term adjustment of 200 days based on the following facts:

### **Case Law**

In *Wyeth v. Dudas*, 2008 U.S. Dist. LEXIS 76063 (D.D.C. 2008), the District Court of the District of Columbia addressed the United States Patent and Trademark Office (USPTO) interpretation of 35 U.S.C. § 154(b)(2). The Court granted summary judgment in favor of Wyeth, determining that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the § 154(b)(1)(A) and § 154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) only occurs if a 35 U.S.C. § 154(b)(1)(A) period and a 35 U.S.C. § 154(b)(1)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(1)(A) period that falls outside of the 35 U.S.C. § 154(b)(1)(B) period in addition to the 35 U.S.C. § 154(b)(1)(B) period itself.

### **Relevant Dates**

The above identified application has a 35 U.S.C. §371 filing date of February 6, 2006.

The first Office Action, which was a Restriction Requirement, was mailed on June 6, 2007, resulting in a PTO delay of 62 days beyond the 14 months provided by 35 U.S.C. §154(b).

A Response to Restriction was filed by Patentee on August 10, 2007.

An Office Action was mailed October 12, 2007.

A Response by Patentee was filed March 5, 2008, resulting in an applicant delay of 53 days.

An Office Action was mailed June 6, 2008.

A Response by Patentee was filed December 1, 2008, resulting in an applicant delay of 86 days.

A Final Office Action was mailed March 9, 2009.

A Response by Patentee was filed April 20, 2009.

A Notice of Allowance was mailed June 24, 2009.

The issue fee was paid September 24, 2009.

The patent issued November 10, 2009.

Accordingly, the total PTO adjustment based on delay under 35 U.S.C. § 154(b)(1)(A) is 62 days.

The 35 U.S.C. § 154(b)(1)(B) period for US Patent 7,615,609 began on February 6, 2009 (three years after the filing date of February 6, 2006) and ended on the date of issuance, November 10, 2009. The 35 U.S.C. § 154(b)(1)(B) period is 277 days.

There was no 35 U.S.C. § 154(b)(1)(A) delay that occurred within this 35 U.S.C. § 154(b)(1)(B) period that should be excluded from the patent term adjustment calculation under the holding of *Wyeth v. Dudas*.

Accordingly, the sum of the 35 U.S.C. § 154(b)(1)(B) and non-overlapping 35 U.S.C. § 154(b)(1)(A) delay is  $(62 + 277 \text{ days}) = 339 \text{ days}$ .

Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the period of applicant delay, which is 139 days.

Accordingly, the correct patent term adjustment for the above identified application is 200 days (the difference between the total period of PTO delay under 35 U.S.C. § 154(b)(1) and applicant delay under 35 U.S.C. § 154(b)(2)(C)).

The PTA printed on the front of US 7,615,609 is only 136 days, which the USPTO is presumed to have calculated using the method considered proper before the holding of *Wyeth v. Dudas*. Applicants therefore respectfully request reconsideration of the PTA listed on the front of US 7,615,609.

**B. Terminal Disclaimer**

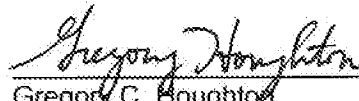
The above-identified patent is not subject to a Terminal Disclaimer.

**C. Reasonable Efforts**

Any applicant delays under 37 C.F.R. § 1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. § 1.704.

Respectfully submitted,

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Date: January 8, 2010